From: Teva Watch
To: David Bonilla
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Tuesday, September 4, 2018

Top News

3 Growth Stocks at Deep-Value Prices

(9/3, Timothy Green, Nicholas Rossolillo, And Todd Campbell, The Motley Fool) ...It's anyone's guess if **Teva** Pharmaceutical's restructuring will succeed or how long Berkshire Hathaway will hold onto its shares, but I think the odds of this being a profit-friendly investment for long-term investors are good enough to add this company to portfolios... Full

9 High-Risk Stocks to Buy for Massive Rewards

(8/31, Vince Martin, InvestorPlace) ...It's a risky path, but if it works **TEVA** could double simply by reaching a higher multiple and removing bankruptcy fears... Full

Israel's Teva Pharm Workers in Protest Against Plant Sale amid Debt

(9/3, Mu Xuequan, Xinhua) ...Some 250 workers of Israel's **Teva** Pharmaceutical, the world's largest generic drugmaker, launched a strike on Sunday to protest against the debt-laden company's plan to sell the plant...The General Federation of Labor in Israel "Histadrut" said that it supports the workers' strike and added that "we regret that **Teva** management does not understand that in far places such as Kiryat Shmona, the employment alternative for workers is almost non-existent." **Teva** said that they are working to sell the plant as a live business that ensures the continuity of the employees, as part of the reorganization process... Full

DOJ, MassBio Back Helsinn In High Court On-Sale Bar Fight

(8/31, Dani Kass, Law360) ...The U.S. Department of Justice, the Massachusetts Biotechnology Council and nine other amici urged the justices to overturn a Federal Circuit decision expanding the America Invents Act's on-sale bar, saying it conflates confidential development agreements for public disclosures and will harm all but the largest drug companies... Paid Sub. Req'd

U. Penn, Lilly Battle Over Erbitux Among Drug Patent Appeals

(8/31, Greg Langlois, Bloomberg) ...Pfizer is appealing a 2017 Delaware decision finding that all five patents-in-suit covering its ADHD drug Quillivant XR (methylphenidate hydrochloride) are invalid. Pfizer's Quillivant manufacturer, Tris Pharma Inc., took **Actavis** Laboratories Inc. to court in 2014, alleging **Actavis**' generic version infringes the patents. **Actavis**, which **Teva** Pharmaceutical Industries Ltd. acquired in 2016, emerged victorious by convincing the court the patents aren't

patentable due to obviousness... Paid Sub. Req'd

Local Lawsuit Stems from Opioid-Dependent Infant

(9/3, Tim Fenster, Niagara Gazette) ...The lawsuit was filed against the pharmaceutical manufacturers Purdue Pharma, **Teva** Pharmaceutical Industries, Johnson & Johnson, Insys Therapeutics, Endo International and a number of manufacturers owned by those aforementioned companies...A spokesperson for **Teva**, which owns **Actavis** and **Cephalon**, said the company does not comment on ongoing litigation... Full

Tucson Medical Center Suing Opioid Manufacturers, Distributors

(8/31, Natalie Tarangioli, KGUN9) ...The lawsuit alleges the companies were negligent by downplaying the serious risk of addiction, promoting long term opioid use, and using deceptive advertising to sell products to TMC... Full

Industry News

Novartis to Streamline Production in Response to Lower U.S. Prices: NZZ am Sonntag

(9/1, Kirsti Knolle, Reuters) ...Proceeds from the sale of drugs in its key U.S. market declined between 1 and 2 percent last year, Joerg Reinhardt told Swiss weekly NZZ am Sonntag. This was due to discounts pharmaceutical companies have to grant large buyers to sell their drugs in the Unites States, he said in an interview that will be published on Sunday...To increase the operating profit margin of its pharmaceutical business to around 35 percent from the current 32 percent within five years as planned, the group aims to increase its efficiency, the paper said... Full

In Health Care Venture, Berkshire Hathaway Investors See Another Blockbuster for Buffett

(9/4, Casey Ross, STAT Plus) ..."I could easily imagine both Berkshire and Amazon creating products for sale out of their nonprofit," said Steve Wallman, a Berkshire investor and money manager from Madison, Wis. "I'd be shocked if opportunities don't arise from this experiment." Wallman told STAT he sees the health care venture as a way for Berkshire and its partners to validate new ways of delivering care and managing benefits... Paid Sub. Req'd

Key Drug Launches To Plan For In 2019

(9/3, John Davis, Scrip) ...As a supplement to its quarterly Outlook reports, Informa Pharma's Biomedtracker has taken a longer-term look at some key late-stage drugs projected to enter their first markets in 2019. These drugs represent new drug classes, major changes to standards of care, and large market opportunities, say Biomedtracker analysts in a new report, Key Potential Drug Launches In 2019... Paid Sub. Req'd

Can Amgen's New-and-Improved Kyprolis Kick-Start Myeloma Sales?

(8/31, Carly Helfand, FiercePharma) ...The data illustrate "Kyprolis' potential to extend the time patients live without their disease progressing while also providing a more convenient … dosing option for this frequently relapsing and difficult-to-treat cancer," David Reece, Amgen's EVP of R&D, said in a statement, adding that he was proud of a Kyprolis clinical program that has put "a focus on generating additional data to reduce the dosing and administration burden on patients."... Full

Fosun Pharma 'Massively' Fakes API Production Data and Bribes Regulators, Whistleblower Says

(8/31, Angus Liu, FiercePharma) ...In an open letter (Chinese) to the drug regulator in Chongqing,

China, self-claimed employees of Chongqing Pharma Research Institute, a unit of Fosun Pharma, depicted a "chaotic" production scene at the company. It alleged that the firm illegally changed production processes of almost all its APIs, while management pushed employees to fabricate data and manipulate testing readouts to achieve passing results... Full

Peter Goldschmidt to Succeed Claudio Albrecht as STADA's CEO
(9/3, STADA Arzneimittel AG) ...Peter Goldschmidt (53) succeeded Claudio Albrecht as the Chief Executive Officer of STADA Arzneimittel AG ('STADA' or 'the Group') with effect from September 1, 2018... Full

Once Charged with Speeding up Eli Lilly's Slow-Mo R&D Group, Anne White Is Handed the Reins at Lilly Oncology
(8/31, John Carroll, Endpoints News) ...The pharma giant announced that Anne White — who's been playing a high-level role in an attempt to cut drug development times — is taking the reins from Sue Mahony, who's completing her planned retirement from the company today... Full

Do Drug Company Payments to Doctors Influence Which Drugs They Prescribe?
(9/4, Elaine K. Howley, US News & World Report) ...Money is a prime suspect for undue influence, and it's probably no surprise that pharmaceutical companies spend billions annually to influence physicians and other drug prescribers to write more prescriptions for their particular products... Full

Is Big Pharma Really More Evil than Academia?
(8/31, Richard P Grant, The Guardian) ...There are of course legitimate questions to be asked and answered about the drivers of misconduct. And yes, many pharma products seem ridiculously expensive. But this isn't necessarily a reflection of greed, as is commonly assumed... Full

Fake, Low Quality Drugs Come at High Cost
(8/31, Lisa Rapaport, Reuters) ...Researchers examined data from more 350 previous studies that tested more 400,000 drug samples in low- and middle-income countries. Overall, roughly 14 percent of medicines were counterfeit, expired or otherwise low quality and unlikely to be as safe or effective as patients might expect... Full

German Drugmaker Rapped for Recordkeeping Issues
(9/4, James Miessler, Drug Industry Daily) ...The FDA hit German drug and API manufacturer Boehringer Ingelheim with a Form 483 for recordkeeping shortcomings at its Ingelheim am Rhein facility. The company's records did not include a complete inventory of sealed product containers filled with finished drug product, as it did not account for manually rejected containers removed from the production line by operators... Paid Sub. Req'd

A Drug Distributor Flagged a Pharmacy's Suspicious Opioid Orders. A Federal Court Says it Has to Keep Shipping the Pills
(8/31, Lev Facher, STAT Plus) ...The U.S. District Court in Alaska ruled this month that the drug distributor AmerisourceBergen must continue to ship opioids to a pharmacy in Anchorage, Alaska, even though the distributor itself flagged the orders as excessive and suspicious. It is a decision that defies a conventional wisdom developed by Congress, a presidential commission, law enforcement, and a bevy of pending lawsuits, all of which place at least some blame for the country's addiction epidemic on distributors... Paid Sub. Req'd

ADHD Diagnoses May Be Rising in US
(8/31, Reuters Health) ...Between 1997 and 2016, the proportion of children diagnosed with ADHD rose from 6.1 percent to 10.2 percent, researchers reported in JAMA Network Open. Greater awareness of the condition may be a factor, said study coauthor Dr. Wei Bao of the College of Public Health at the University of Iowa... Full

Know Your Judge: Sleet's Court Plays Host to Big Patent Cases
(8/31, Kyle Jahner, Bloomberg Law) ...Patent disputes have dominated Sleet's caseload in Delaware, where roughly two-thirds of Fortune 500 companies are incorporated. More than 850 patent lawsuits have gone before Sleet in the last five years, more than double the total for all other types of cases in his court combined, Bloomberg Law data show. A substantial share of Sleet's cases involve drug and biotech giants like Amgen Inc., Pfizer Inc., Genetech Inc., **Teva** Pharmaceutical Industries Ltd., Merck & Co., and Mylan NV... Full

U.S. Policy & Regulatory News

PBMs' Impact On Drug Prices Probed By House Committee Leaders
(9/3, Cathy Kelly, Pink Sheet) ...The letter offers PBMs an opportunity to describe how price concessions can help seniors access "affordable options in Medicare" and how plans use price concessions to lower the price to consumers for "particularly expensive drugs." But it also seeks explanations for PBM practices that have come under fire, such as "gag clauses," which are contractual arrangements that prevent pharmacists from informing patients when they could get a drug for less if they pay cash rather than use their insurance... Paid Sub. Req'd

House Leaders Ask PBMs to Explain Their Impact on Downstream Drug Costs
(8/31, Evan Sweeney, Fierce Healthcare) ...The panel sent letters to CVS, EnvisionRXOptions, Express Scripts, Humana, Prime Therapeutics, Procare Pharmacy and UnitedHealth Group. A detailed list of questions sought additional transparency about negotiations around list prices, price concessions in Medicare Part D, Medicaid managed care contracts and how contract terms impact the ability to negotiate drug prices. "In addition to providing written answers to the questions above, please provide a copy of any standard contracts used with your clients regarding PBM services referring or relating to federal payers," the lawmakers added... Full

Lawmakers Search for Answers on Oversight of Controversial Drug Discount Program
(9/4, Robert King, Washington Examiner) ...While the administration has called on Congress for more authority, the leadership of the relevant committees believe it already isn't using its full power to oversee 340B. It wants the administration to do a better job of defining what the intent of the program is and the requirements for both participating hospitals and pharmaceutical companies providing the discounts... Full

Patients For Affordable Drugs Honors Gottlieb For His Drug Pricing Work
(8/31, InsideHealthPolicy.com: The Vitals) ...Gottlieb was highlighted "for his achievements and the work underway at the FDA to stop unfair and exploitative drug company tactics that prevent less expensive generics and biosimilars from coming to market," Patients for Affordable Drugs announced Thursday... Paid Sub. Req'd

Is Mistrust of 'Big Pharma' Enough to Help Unseat a Democratic Stalwart in Congress?

(9/4, Lev Facher, STAT) ...Three miles from the sprawling U.S. campus of the pharmaceutical giant Astrazeneca, Kerri Evelyn Harris was campaigning to unseat the man who put it there.Harris's go-to campaign topics include drug pricing, special interests, the opioid crisis — and what she views as the throughline joining all three: the pharmaceutical industry... Full

Inappropriate 'Interchangeability' Requirement for Biosimilars Will Cost the U.S. Billions
(9/4, Vijay Ramakrishnan and Edwin P. Ching, STAT Plus) ...The FDA's mandate is to regulate drug approvals, not the practice of medicine. We assert that the interchangeability requirement is part of the practice of medicine and is best addressed by providers, not by regulations. When the FDA approves a biosimilar based on the safety and efficacy standards it has set forth, that label should then be sufficient for substitution by a specialty pharmacist without the intervention of the prescriber... Paid Sub. Req'd

Biosimilar Medicines Are the Key to Success
(9/3, Dr. Angus B. Worthing, The Hill) ...Should the FDA amend its guidance to require fewer than three switches, in an effort to improve the efficiency of the approval process, patients would be exposed to uncertain risks, and prescriber confidence would be undermined. Released in January of last year, I urge the FDA to finally publish this guidance — without delay... Full

Video: FDA Takes on Opioid Crisis With New Pain Drug Guidelines
(8/31, Bloomberg) ...FDA Commissioner Scott Gottlieb outlines new guidance on pain drug development in the ongoing fight against opioids. He speaks with Bloomberg's Alix Steel on "Bloomberg Daybreak: Americas."... Full

Can Scott Gottlieb Reverse the Opioid Crisis?
(8/31, Dr. Lynn Webster, The Hill) ...We need to keep our eyes wide open to solve the drug problem, and that begins by recognizing that the opioid epidemic is no longer primarily a prescription drug problem. It is an illicit drug problem and it is continuing to worsen... Full

Judge Tosses Pharma Lawsuit Designed to Thwart California Transparency Law
(8/31, Ed Silverman, STAT Plus) ...In explaining his decision, U.S. District Judge Morrison England Jr. ruled that the Pharmaceutical Research and Manufacturers of America failed to show that the court has jurisdiction to hear the case. However, he wrote that the trade group can refile its case if it can prove that any potential harm to drug makers falls "outside the realm of conjecture," a step that would give PhRMA standing to press it case. A PhRMA spokeswoman wrote us that the judge gave the trade group "an opportunity to amend our complaint, and we continue to have strong concerns about the constitutionality" of the law... Paid Sub. Req'd

Big Data In Medicines Regulation Will Need 'Considerable Change In Mindset'
(8/31, Maureen Kenny, Pink Sheet) ..."A considerable change in mindset across the board" will be needed in a new era of drug development where precision medicine, real-world data gathering and the use of big data are the norm. That's the view of Thomas Senderovitz, Danish Medicines Agency head and until recently chair of the joint Heads of Medicines Agencies/European Medicines Agency Big Data Task Force. Big data is not the only driver. The fast pace of change and convergence of technologies are also key, says Senderovitz... Paid Sub. Req'd

Rein in Medicaid Rx Managers

(9/2, Toledo Blade) ...PBMs need to be managed so they save the state money without gouging the pharmacists and without excessively rewarding themselves. The way to do this is for the state to oversee the PBMs' records with more transparency, rather than taking their word for it... Full

FDA Finalizes Guidance on Physiologically Based Pharmacokinetic Analyses
(8/31, Ana Mulero, RAPS) ...The final guidance has yet to be made public. But the Federal Register notice suggests the draft version, revealed in December 2016, received a number of revisions that took into consideration at least some of the issues and concerns raised during the comment period, which was closed with about a dozen comments, including from the European Medicines Agency (EMA)... Full

International News

Brexit Likely To Force 'Refocusing' Of Ambitious EU Network Strategy
(9/3, Maureen Kenny, Pink Sheet) ..."We're not discarding anything but we will have to temporarily refocus," according to Thomas Senderovitz, Danish Medicines Agency head and chair of the HMA management group. "It's a complex question and I don't want to speak on behalf of EMA," Senderovitz emphasized in a wide-ranging interview with the Pink Sheet... Paid Sub. Req'd

Pfizer Says Getting Ready for Brexit Will Cost $100m
(9/4, Joanna Bourke, London Evening Standard) ...It warned the result of Britain's "complex" negotiations to leave the bloc "may pose certain implications to our research, commercial and general business operations in the UK and the EU". New York-headquartered Pfizer, which generated around 2% of its 2017 $53 billion revenues from the UK, said potential implications were linked to the approval and supply of products... Full

Britain Loses Medicines Contracts as EU Body Anticipates Brexit
(9/2, Lisa O'Carroll, Hannah Devlin, The Guardian) ...The decision by the European Medicines Agency to cut Britain out of its contracts seven months ahead of Brexit is a devastating blow to British pharmaceutical companies already reeling from the loss of the EMA's HQ in London and with it 900 jobs... Full

European Ruling May Bring Generic Truvada a Step Closer
(8/31, Matthew Royle & Paul England, PharmaTimes) ...Although the decision of the Patents Court is still awaited, if it takes the same view as the CJEU on the facts invalidation and revocation of the SPC would open up the UK market to potential competition from generic versions of Truvada... Full

UK: Napp: Leading the Way in the Biosimilars Era
(9/3, Paul Clark, PharmaTimes) ...There is no question that biosimilars have been a success in the NHS, with over 20 different biosimilars available in the UK market. But despite this, we still see a lack of confidence in biosimilars amongst some NHS decision makers and HCPs. We are working hard to actively change this through biosimilar education, building partnerships and engaging with key stakeholders... Full

Irish Access for MS Drug Offering 'Freedom' and 'Savings'
(9/3, The Pharma Letter) ...Ireland is the latest European country where patients with highly-active relapsing multiple sclerosis (MS) will have access to Mavenclad (cladribine). These tablets, from

German drugmaker Merck KGaA, are the first MS treatment that can help reduce relapses for up to four years with a maximum of 20 days oral treatment, taken in the first and second year... Paid Sub. Req'd

Denmark Targets Industry Growth With New Scientific Advice Service
(9/3, Neena Brizmohun, Pink Sheet) ...In an Aug. 31 statement announcing the new service, the DMA said: "The aim of our National Scientific Advice meetings is to promote an open and active dialogue on the issues presented to us, so that the scientific advice given is as competent and effective as possible." The agency is offering scientific advice via face to face meetings, telephone conference or in writing, depending on the nature and complexity of the issues to be addressed... Paid Sub. Req'd

Art Of War: Why Pharma Must Do Digital Dance In China
(9/4, Brian Yang, Scrip) ...Already a global front-runner in e-commerce and mobile technology, China is embarking on a new journey to prep its health sector for a digital transformation. While there is no lack of digital innovation among pharma companies, what's happening now in the country may represent a new health trend that has not been seen before, some observers say... Paid Sub. Req'd

China Accepts First Application for Humira Biosimilar
(9/4, BioSpectrum Asia) ..."Bio-Thera is proud to file the first BLA for a proposed Humira biosimilar in China," said Shengfeng Li, Chief Executive Officer of Bio-Thera Solutions. "We expect BAT1406 to be the first Humira biosimilar to be approved for the China market, allowing more patients to have access to an important autoimmune therapy at a more affordable cost."... Full

GlaxoSmithKline Scientist Cops a Guilty Plea in Scheme to Sell the Pharma Giant's Drug Research in China
(9/4, John Carroll, Endpoints News) ...More than two years after a senior GlaxoSmithKline scientist in Philadelphia was charged with a plot to steal trade secrets and sell the work in China, Chinese-American chemist Yu Xue has now pleaded guilty to a single count against her... Full

Multinational Pharma Increasing Operations and Investment in India
(9/1, The Pharma Letter) ...Experts point out India's population is growing rapidly, as is its economy, creating a large middle class with the resources to afford Western medicines... Paid Sub. Req'd

Expanding from Generics to Biosimilars in India
(9/4, Allie Nawrat, Pharmaceutical Technology) ...Biosimilars are subject to stringent clinical timelines because biologic products are subject to clearly defined regulatory procedures that require large-scale, comprehensive clinical programmes proving their safety and efficacy in treating the indicated disease. The process needs to be highly controlled to ensure quality across the system... Full

Opinion | The Need for Growth in Indian Biosimilars
(9/3, Srividya Jagannathan, Live Mint) ...It is increasingly clear that the segment of the pharmaceutical market where we will see demand grow the fastest in the coming years is products that treat non-communicable diseases. We should, therefore, strive to promote strong, indigenous producers of complex generics and biosimilars as this has enormous potential to improve public

health in emerging markets... Full

India: Prescribe Generic Medicines from Jan Aushadhi Centres: Govt to Dist
(9/2, Ishita Bhatia, Times of India) ...As many as 100 such Jan Aushadhi Kendras run under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana Kendra (PMBJPK) have come up in Uttar Pradesh, with an aim to cut the cost of medicines by at least 90%... Full

Global Ban on Promotional Aids Adds Burden on Local Drugmakers
(8/31, So Jae-hyeon, Korea Biomedical Review) ...Especially after the government toughened rules to punish illegal rebates and the introduction of anti-graft law, pharmaceutical firms became more obsessed with offering tailored promotional aids. For example, they give doctors chargeable hot packs in the winter and portable mini fans in the summer... Full

UAE: Generic Drugs Will Benefit Both Patients and Providers
(9/1, The National) ...It hints at an anomaly in the UAE's otherwise competitive healthcare system, which allows some pharmaceutical companies to maximise profits at the expense of patients.If this policy is to be successful, a mindset change is required among those who assume that generic drugs are not as effective as branded pharmaceuticals. The Department of Health has given options for those who still prefer brands to pay the difference... Full

GlaxoSmithKline Targets 2020 for Planned UAE Facility
(9/2, Ed Clowes, Gulf News) ..."In the UAE, we are looking at options," said Sally Storey, GSK's general manager for the Gulf, adding that instead of building a facility from scratch, the drugmaker was leaning towards a partnership. "It may be that we don't build something, we may look [to go] through a partnership. "We are relatively advanced in that right now. We're looking at about six products initially."... Full

Industry Involvement in Panel for Australia's Life Saving Drugs Program
(8/31, The Pharma Letter) ...The Australian government has said that its establishment of an expert panel for the Life Saving Drugs Program (LSDP) will improve the scheme's ability to provide free medicines for rare and life-threatening diseases to those who need them... Paid Sub. Req'd

Ukraine Widens Access To Essential Drugs For CV, Diabetes & Asthma
(8/31, Ian Schofield, Pink Sheet) ...Access to essential medicines is expected to rise significantly in Ukraine after the health ministry added 22 new products to the list of medicines fully or partially reimbursed under its affordable medicines program... Paid Sub. Req'd